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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,123	09/06/2001	Hiroaki Nakagami	213445US0PCT	6130

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EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/05/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/926,123

Applicant(s)

NAKAGAMI ET AL.

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

## DETAILED ACTION

### *Receipt of Papers*

Receipt is acknowledged of the Priority Papers, the Preliminary Amendment A, and the Information Disclosure Statement, received by the Office September 6, 2001, November 1, 2001, and December 7, 2001.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 14-16, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/17667 Yajima *et al.*. Yajima *et al.* disclose a composition for oral preparation, which comprises a complex formed by dispersing or dissolving an unpleasantly tasting drug and a polymer in a substance having a low melting point, and a sugar alcohol (abstract). Yajima *et al.* teach that the composition is excellent in masking unpleasantly tasting drugs and has excellent performance in biological use. More specifically, Yajima *et al.* teach that the unpleasantly tasting drug can be erythromycin, or clarithromycin, among others (page 4, paragraph 2). Yajima *et al.* teach that the substance having a low melting point is a water-insoluble or water sparingly soluble substance with a melting point of 40 to 120 degrees Celsius (page 4, paragraph 5), for example, hydrogenated oil, stearyl alcohol, glycerin fatty acid ester (page 5, paragraph 1). Yajima *et al.* also teach that the sugar alcohol includes sorbitol, xylitol, and maltitol (page 5,

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paragraph 3), and that it is present at between 10 and 70 % by weight (page 5, paragraph 4).

Yajima *et al.* also teaches the process of granulation through spray drying (see examples 1-13).

Lastly, Yajima *et al.* teaches the composition as a dosage form for oral preparations. Therefore, the teachings of Yajima *et al.* anticipate applicant's instant claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yajima *et al.*

Yajima *et al.* are discussed above as teaching a composition for oral preparation which comprises a unpleasantly tasting drug, a substance with a low melting point, and a sugar alcohol.

Yajima *et al.* do not specifically teach each and every one of applicant's claimed active agents. However, Yajima *et al.* does teach some of the actives claimed by applicant. It is the position of the examiner that one of ordinary skill in the art would have been motivated to use any active which is known to have an unpleasant taste, in a formulation whose sole purpose is to mask the unpleasant taste of the active agent. The expected result would be a dosage form without an unpleasant taste.

Additionally, Yajima *et al.* do not teach the specific particle size of the granulated product. It is the position of the examiner that one of ordinary skill in the art would have been

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motivated to create a granulated product, with taste masking capabilities, regardless of the particular particle size, based on the teachings of Yajima *et al.*. The reference clearly teaches the process of granulation (See examples 1-13), and absent a clear showing of criticality, the determination of the particular particle size is within the skill of the ordinary worker as part of the process of normal optimization. The expected result would be a successful granulated dosage form with taste masking capabilities.

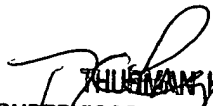
### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam  
Patent Examiner  
Art Unit 1615  
November 4, 2002

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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